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For Immediate Release

Arteriocyte awarded FDA IDE approval to initiate clinical evaluation of MAGELLAN® Bio-Bandage™ in Acute Deep Partial Thickness Thermal Injuries.

Cleveland, O.H., May 2, 2014 – Arteriocyte, Inc., a leading biotechnology company with offices in Cleveland, Ohio and Hopkinton, Massachusetts, announced approval from the Federal Drug Administration (FDA) to initiate a Phase I, clinical trial using its MAGELLAN® Bio-Bandage™ technology in the treatment of Acute Deep Partial Thickness Thermal Injuries. The FDA Investigational Device Exemption (IDE 15921) allows Arteriocyte to initiate clinical evaluation of Autologous Platelet Rich Plasma use in thermal injuries. The IDE approval marks another major milestone in Arteriocyte's partnership with the Biomedical Advanced Research and Development Authority (BARDA), to advance the use of PRP in the setting of mass casualty thermal injuries. The MAGELLAN® Bio-Bandage™ is an autologous intervention designed to minimize the severity of the burn wound, reduce the immediate need for surgical intervention when a skin graft is required, and improve the wound's healing trajectory.

"Our current IDE approval represents another important step along the pathway toward helping patients with thermal injury. The use of PRP has the potential to improve the quality of burn care and clinical outcome, with the added benefit of reducing the stress on resources in a mass casualty. We expect that successful clinical outcomes will result in more patients having access to MAGELLAN® Bio-Bandage™ and we are honored to be assisting BARDA in their readiness efforts to mobilize rapid medical care in the setting of mass casualty that results in thermal injuries." said Arteriocyte CEO, Don Brown.

Thermal Wound Treatment
Treatment of severe burns is a rapidly emerging segment of advanced wound care. Each year, in the United States, approximately 1.1 million burn injuries require some level of medical attention. The current course of treatment involves dressings and creams that provide physical protection of the burn and reduce the bacterial burden. Many of these burns subsequently convert to full thickness during the hours and days following injury, resulting in the need for a skin graft. To date, no single therapy has shown an ability to induce healing of the burn wound early following injury in order to prevent the conversion of a partial thickness burn injury to full thickness and one that requires a skin graft. Current literature suggests that growth-factor rich platelet rich plasma (PRP) plays a role in stimulating new blood vessel growth and recruiting keratinocytes to re-epithelialize wounds while decreasing pain and risk of infection. The MAGELLAN® Bio-Bandage™ is rapidly produced at the bedside using a patient's own blood, and may potentially reduce the need for a skin graft while improving tissue healing following a thermal injury.

About Arteriocyte
Arteriocyte, a leading clinical stage biotechnology company, is dedicated to developing novel cellular products and medical devices to help patients heal faster. Arteriocyte leverages its expertise in stem cell and tissue engineering in order to develop a broad portfolio of cell based therapeutics to improve patient outcomes. In October of 2007, Arteriocyte partnered with DW Healthcare Partners and Comerica to create Arteriocyte Medical Systems Inc., in order to commercialize and distribute novel medical devices and point of care surgical solutions. Arteriocyte Medical Systems manufactures and distributes the MAGELLAN® Autologous Platelet Separator System.

About BARDA
The mission of the Biomedical Advanced Research and Development Authority (BARDA) is to develop and procure medical countermeasures that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases. Specifically, BARDA supports the advanced development and procurement of drugs, vaccines and other products that are considered priorities for national health security.

Contact Information
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